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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/930,715	08/14/2001	Moncef Jendoubi	266/226	1686

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EXAMINER	
TRAN, MY CHAU T	
ART UNIT	**PAPER NUMBER**
1639	

DATE MAILED: 02/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/930,715	JENDOUBI, MONCEF	
	Examiner	Art Unit	
	MY-CHAU T. TRAN	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 July 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Application and Claims Status

1. Applicant's response filed 11/9/05 is acknowledged and entered.

2. The amendment filed on 02/07/2005: amended claims 14 and 17.

3. The amendment filed on 04/23/2004: cancelled claims 22, and 23; and amended claims 14-16.

4. The amendment filed on 08/28/2003: cancelled claims 1-11; and added claims 14-23.

5. The amendment filed on 03/18/2003: cancelled claims 12-13; and amended claims 1 and 3.

6. Claims 14-21 are pending.

7. Claims 14-21 are under consideration in this Office Action.

Maintained Rejection(s)

Claim Rejections - 35 USC § 102

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 14, and 17-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Chenchik et al. (US Patent 6,087,102).

10. Claims 14-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Bandaru (US Patent 6,462,187 B1; *filing date of 6/15/2000*).

11. Claims 14-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Wagner et al. (US Patent 6,329,209 B1; *filing date 7/14/1999*).

Response to Arguments

12. Applicant's arguments directed to the rejection under 35 USC 102(b) as being anticipated by Chenchik et al. (US Patent 6,087,102) for claims 14, and 17-20 were considered but they are not persuasive for the following reasons.

> Chenchik et al. disclose and arrays of polymeric targets associated with the surface of the support and the method of using the array in high through gene expression analysis (see e.g. Abstract; col. 2, lines 3-11, and 51-62; col. 11, lines 3-23). The polymeric targets are bipolymeric compounds that include naturally occurring polymeric compounds or mimetics or analogues of naturally occurring polymeric compounds, and the bipolymeric compounds includes peptides, polypeptides and proteins wherein they derived from cells or tissue exacts, which are derived from normal, disease, or condition state such as cancer or exposure to toxic agents (see e.g. col. 3, lines 13-20, and lines 51-64). The polymeric targets are pattern on the support in a variety of configurations wherein each polymeric targets at a discrete location (see e.g. col. 5, lines 35-47). The method of using the array in high through gene expression analysis comprises the step of preparing the probe, contacting the probe with the array under conditions sufficient for probe to bind with corresponding target, removal of unbound probe from the array, and detecting the bound probe (see e.g. col. 8, line 55 thru col. 10, line 45). The probes include peptidic probes such as polyclonal antibodies and a labeled with a detectable label (see e.g. col. 9, lines 18-65). The assay determines both the expression level and the size of the target bound by the probe (see e.g. col. 11, lines 3-23). Thus, the method of Chenchik et al. anticipates the presently claimed invention.

Applicant argues that the reference of Chenchik et al. does not anticipate the presently claimed invention because Chenchik et al. do not teach or suggest the method steps of a)

"*providing a plurality of antibodies each having a signaling element when each member of the plurality of antibodies is identified as having specific binding affinity to an expression product of the gene sequence*" and "*identifying differential gene expression between the at least two distinct biological conditions by correlating differences in the antibody binding reaction in the at least two samples with expression of the gene sequence identified with the member of the plurality of antibodies*". Thus, the reference of Chenchik et al. does not anticipate the presently claimed invention.

Applicant's arguments are not convincing since the teachings of Chenchik et al. do anticipate the invention of the instant claims. It is the examiner position is that Chenchik et al. do disclosed the instant claimed 'providing' step of instant claim 14 (col. 9, lines 25-30 and 58-61) and the claimed 'identifying' step of instant claim 14 (col. 11, lines 12-23). That is Chenchik et al. do disclose that the binding reaction of a particular antibody is linked to a particular gene for the label, which associated with the probe (antibody), provide a signal only when the probe is specifically bound to the target molecule (gene)(col. 9, lines 58-61; col. 11, lines 12-23). Therefore, the teachings of Chenchik et al. do anticipate the invention of the instant claims, and the rejection is hereby maintained.

13. Applicant's arguments directed to the rejection under 35 USC 102(b) as being anticipated by Bandaru (US Patent 6,462,187 B1; *filing date of 6/15/2000*) for claims 14-21 were considered but they are not persuasive for the following reasons.

> Bandaru discloses a method of comparing the level of expressed polypeptide before and after treatment of the disorder (e.g. biological conditions) (see e.g. col. 4, lines 9-13). The disorder includes cancerous condition (see e.g. col. 10, lines 21-55). The method of detection comprised of detecting the binding interaction of the antibody specific to the expressed polypeptide (see e.g. col. 37, lines 36-47). The method comprise of a two dimensional array having a plurality of addresses,

each address of the plurality is positionally distinguishable from each other address of the plurality (see e.g. col. 4, lines 35-45; col. 51, lines 37-67). Each address of the plurality can have a unique capture probe such as polypeptide, e.g. an antibody specific for the polypeptide. The plurality of addresses includes at least 10, 100, 500, 1,000, 5,000, 10,000, 50,000 addresses (see e.g. col. 49, lines 14-16). The array can be use to assay gene expression in a tissue to ascertain tissue specificity of genes in the array (see e.g. col. 49, lines 62-64) or to monitor expression of one or more genes in an array with respect to time for ascertaining differential expression patterns of one or more genes in normal or abnormal cells (see e.g. col. 50, lines 32-45). Additionally, the method of Bandaru does disclose the step of containing human protein samples in an array (see e.g. col. 4, lines 9-13) and refer to the analysis of gene expression information in a tissue sample is derived from the differential binding reactions at two discrete sites of the array (see e.g. col. 4, lines 35-40, and 43-45; col. 49, lines 62-64). The method of Bandaru also disclose detecting the signal generated from a labeled attached to the antibody that binds to the probe of the array (see e.g. col. 51, lines 8-67). Therefore the method of Bandaru anticipated the presently claimed method.

Applicant alleges that the reference of Bandaru does not anticipate the presently claimed invention because Bandaru do not teach or suggest the method steps of a) "*providing a plurality of antibodies each having a signaling element when each member of the plurality of antibodies is identified as having specific binding affinity to an expression product of the gene sequence*" and the method step of claim 15 wherein the antibodies are raised by in vivo immunization of a gene sequence. Thus, the reference of Bandaru does not anticipate the presently claimed invention.

Applicant's arguments are not convincing since the teachings of Bandaru do anticipate the invention of the instant claims. It is the examiner position is that Bandaru does disclose the instant claimed 'providing' step of instant claim 14 (col. 51, lines 8-67) and the method step of claim 15 (col. 26, line 1 thru col. 30, line 10). That is Bandaru does disclose that the binding reaction of a particular antibody is linked to a particular gene for the label, which associated with the probe (antibody), provide a signal only when the probe is specifically bound to the target molecule (gene)(col. 50, lines 1-7; col. 51, lines 32-36 and 60-63). Therefore, the teachings of Bandaru do anticipate the invention of the instant claims, and the rejection is hereby maintained.

14. Applicant's arguments directed to the rejection under 35 USC 102(b) as being anticipated by Wagner et al. (US Patent 6,329,209 B1; *filing date 7/14/1999*) for claims 14-21 were considered but they are not persuasive for the following reasons.

> Wagner et al. disclosed a method of comparing the protein expression of two cells or a population of cells that have been exposed to different conditions (see e.g. col. 37, lines 19-67). The method comprises an array of protein-capture agents arranged in discrete, known regions of patches (see e.g. col. 9, lines 66-67 to col. 10, lines 1-12). The array can have any number of a plurality of different protein-capture agents (see e.g. col. 11, lines 1-11). For instance, an array comprise of about 10,000 patches would comprise of about 10,000 different protein-capture agents (see e.g. col. 11, lines 28-33). Therefore, the number of different protein-capture agents on an array will vary depending on the application desired (see e.g. col. 11, lines 12-13). The protein-capture agent would include biomolecule such as protein or polynucleotide (see e.g. col. 4, lines 48-67) and would binds specifically to the antibody of interest (see e.g. col. 12, lines 48-52). Additionally, the method of Wagner et al. does perform the method step of containing two tissue samples onto an array to obtain gene expression analysis because Wagner et al. define an array as an arrangement of entities in a pattern on a substrate (see e.g. col. 6, lines 61-64) and the array have plurality of different protein-capture agents (see e.g. col. 11, lines 1-4) (i.e. pluralities of different protein-capture agents are arranged in a pattern on a substrate). Wagner et al. discloses that protein-capture agents are proteins in a cell that specifically binds to another protein such as an antibody (see e.g. col. 12, lines 50-52). The method of Wagner et al. also disclose detecting the signal generated from a labeled attached to the antibody that binds to the protein-capture agents of the array (see e.g. col. 34, lines 10-43). Therefore the method of Wagner et al. anticipates the presently claimed method.

Applicant contends that the reference of Wagner et al. does not anticipate the presently claimed invention because Wagner et al. do not teach or suggest the method steps of a) "*providing a plurality of antibodies each having a signaling element when each member of the plurality of antibodies is identified as having specific binding affinity to an expression product of the gene sequence*" and the method step of claim 15 wherein the antibodies are raised by in vivo immunization of a gene sequence. Thus, the reference of Wagner et al. does not anticipate the presently claimed invention.

Applicant's arguments are not convincing since the teachings of Wagner et al. do anticipate the invention of the instant claims. It is the examiner position is that Wagner et al. do disclosed the instant claimed 'providing' step of instant claim 14 (see e.g. col. 34, lines 10-43; col. 36, lines 51-65; col. 37, lines 54-67) and the method step of claim 15 (col. 26, line 37 thru

col. 28, line 26). That is Wagner et al. do disclose that the binding reaction of a particular antibody is linked to a particular gene for the label, which associated with the probe (antibody), provide a signal only when the probe is specifically bound to the target molecule (gene)(see e.g. col. 36, lines 51-65; col. 37, lines 1-36). Therefore, the teachings of Wagner et al. do anticipate the invention of the instant claims, and the rejection is hereby maintained.

Conclusion

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 571-272-0810. The examiner can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mct
February 17, 2006

PADMA[illegible]ONNALURI
PRIMARY EXAMINER